DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	11/17-21/2025-11/27/2025
	FEI NUMBER: 3008386908

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Subbarao Koppula, Vice President Operations

FIRM NAME	STREET ADDRESS
Gland Chemicals Private Limited	B-11 Plot No B-3, Sipcot Industrial Park & B-6 to B-18
CITY, STATE, ZIP CODE, COUNTRY: Chennai, Tamil Nadu, 602117, India	TYPE ESTABLISHMENT INSPECTED: Sterile Drug Product Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM **WE** OBSERVED:

OBSERVATION 1

Separate or defined areas to prevent contamination or mix-ups are deficient regarding the manufacturing and processing operations.

Your Quality Unit failed to perform a comprehensive assessment of the risks associated with potential cross contamination throughout the facility/common areas. Your firm is engaged in the manufacturing of (b) (4) sterile drug (b) (4) (e.g., (b) (4) (b) (4)

For example, there are no adequate containment practices regarding movement of personnel, handling of laboratory control samples, and production documents, through common areas. Furthermore, your firm failed to conduct a risk assessment to justify the sampling points of your cross-contamination monitoring program to ensure that the sterile (b) (4) products are not cross-contaminated.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Alan A. Rivera, Investigator Jose E. Melendez, DDC Investigator Angelica M. Hernandez, Investigator	November 27, 2025

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Chennai, Tamil Nadu, 602117, India	Sterile Drug Product Manufacturer

A. The Quality Control and microbiology laboratory located in (b) (4) Block use a non-dedicated (b) (4) to transfer (b) (4) samples, in-process, raw material, stability, and finish product samples to QC laboratory.

B. (b) (4) in-process finished product and stability samples pending for QC analyses are stored in a common area (control room (b) (4) After receipt, the samples are assigned to your Quality Control laboratory analysts that perform samples preparation and analytical tests for (b) (4) products simultaneously.

C. (b) (4) batch production control records and EM control records are sent to office (b) (4) for Quality Assurance (QA) review. This office is located inside the (b) (4) Block. These manufacturing records are transferred from the (b) (4) Block to office (b) (4) through the same main entrance and hallways that (b) (4) manufacturing employees use to access their respective (b) (4) manufacturing areas, creating a potential cross-contamination.

D. As per your General Manager QA, your Quality Assurance representatives, Quality Control analysts and (b) (4) manufacturing operators use a common canteen during lunch. Your Quality Control analysts responsible to prepare and test laboratory samples for (b) (4) along with your Quality Assurance employees that review (b) (4) BMRs, use the same hallways and join the (b) (4) manufacturing operators during lunch creating a potential source for cross-contamination. Moreover, it was informed by your General Manager- QA, that your QC laboratory has not validated analytical test methods to detect and quantify the presence of (b) (4) in (b) (4) sterile drug (b) (4) and vice versa.

E. Your "Cross Contamination Study Program", SOP Number: QA050-02, Effective Date: June 27, 2025, is deficient in that does not consider personnel monitoring to ensure that personnel flow is not introducing cross-contamination into the (b) (4) Blocks. Furthermore, there is no risk assessment to justify that the current sampling locations are scientifically sound to ensure

that the established sampling points and areas represent the worst locations. The current sampling locations were selected randomly.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

A. The aseptic process simulation (media fill) studies carried out in the (b) (4) blocks are inadequate. During our review of the media fill batch records used to qualify the filling lines in the (b) (4) aseptic processes, we found that an assignable cause is not provided for all vials rejected during filling and stoppering activities. The rejected vials summarized below were not included with the incubation of the aseptically filled batches.

(b) (4)

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(b) (4)

[redacted]

B. Your Quality Unit failed to perform a comprehensive assessment of the risks associated with aseptic processing operations.

Specifically, your Quality Unit did not conduct a formal, documented risk assessment to determine the frequency, duration, and contamination risk associated with inherent and corrective aseptic process interventions that might occur during your aseptic filling operations. As a result, the (b) (4) blocks lack a scientifically sound basis for assessing the impact of operators' interventions on aseptic processing lines, establishing adequate EM controls, and ensuring that aseptic processing is performed under process conditions designed to prevent microbial contamination.

C. There is no assurance that corrective interventions requiring the removal of glass vials from different zones of the filling line are accurately simulated during aseptic process simulation (APS) studies.

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For example, the following corrective interventions (e.g., removal of toppled vials from (b) (4) removal of toppled vials from (b) (4) conveyor, removal of toppled vials from (b) (4) conveyor, removal of toppled vials from the (b) (4) conveyor and removal of broken vials from conveyor under filling station) require the vials are removed during the intervention. According to your production department head, manufacturing operators simulate the interventions without removing the vials. As a result, the APS does not adequately challenge the aseptic skills of operators or their performance under the worst conditions to correctly establish the duration of interventions. This practice could call into question the validity of the APS as an indicator of process sterility assurance.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Smoke studies conducted in the (b) (4) vial filling lines (b) (4) do not accurately reflect the conditions that would be encountered during routine manufacturing processes. Technicians involved in the studies show multiple instances of poor aseptic technique and non-compliance with established procedures observed, including but not limited to:

Smoke study (b) (4) Block:

A. During the (b) (4) interventions, fix the (b) (4) stopper length chute and fix the (b) (4) (b) (4) the manufacturing operator was observed sanitizing his gloved hands immediately prior to performing the finger-dab monitoring. This practice may reduce microbial recovery and does not reflect the true aseptic conditions of the gloves during routine operations.

B. During the (b) (4) intervention, cleaning of (b) (4) spillage under Grade A, it was observed that the manufacturing operator did not adequately sanitize the (b) (4) hose used to remove the sterile

(b) (4) near the (b) (4) prior to introducing it into the ISO 5 area. In addition, the hose is kept at the edge of the (b) (4) LAF (filling room classification is Grade B) without any protective covering on the hose opening, exposing aseptic core area (ISO 5) to potential contamination.

C. It was observed that airflow laminarity is not maintained during the demonstration of airflow direction among filling line (ISO 5 area), (b) (4) LAF and (b) (4) LAF. The (b) (4) LAF is positioned at the front side of the filling line during the assembly process, and both the filling line and the (b) (4) LAF are kept with the (b) (4) throughout the assembly interventions. The video shows an interruption in the unidirectional airflow.

Smoke study (b) (4) Block:

A. During the (b) (4) intervention, remove the protective cover from the stopper bowl and replace used forceps with new one, it was noted that only the manufacturing operator positioned at the front side of the filling line was subjected to finger dab monitoring. The operator positioned at the rear side of the line, who also participated in the intervention, was not monitored. This practice fails to ensure that all personnel involved in this intervention are assessed for potential contamination risk.

B. During the (b) (4) intervention, loading of (b) (4) API canister, it was observed the design of the dispensing area (ISO 5 area) does not allow the manufacturing operator to perform the loading process of the canister smoothly or with deliberate, controlled movements. This restricted space increases the risk of unintentional contact of the (b) (4) with equipment and surfaces, which may compromise aseptic technique. At the conclusion of the intervention, it was further observed that the manufacturing operator used the (b) (4) to remove the (b) (4) (b) (4) This action may create a risk of cross-contamination between (b) (4) and is inconsistent with adequate aseptic (b) (4) handling techniques expected in controlled environments.

C. During the (b) (4) intervention (b) (4) loading the API canister, it was observed that the fingers and sleeve of the operator (b) (4) contacted the (b) (4) stopper of sterile (b) (4) filled canister. This action represents an unacceptable breach of aseptic technique and potentially increase the risk of contaminating the sterile API. At the conclusion of the intervention, it was further observed that the manufacturing operator removed the (b) (4) using the (b) (4) which is inconsistent with adequate (b) (4) removal procedure and presents an additional potential risk of cross-contamination.

D. During the (b) (4) intervention, opening of (b) (4) valve to load API into (b) (4) it was observed that the manufacturing operator removed the (b) (4) using the (b) (4) (b) (4) This action may create a risk of cross-contamination between (b) (4) and is inconsistent with adequate aseptic (b) (4) handling techniques expected in controlled environments.

OBSERVATION 4

Established sampling plan and test procedures are not followed.

We reviewed the biometric access control system (eSSL Security at Fingertips) for the (b) (4) (b) (4) where the (b) (4) system is located, and (b) (4) samples are collected. We observed the following deficiencies:

A. On (b) (4) your Quality Assurance employee ID: (b) (6) documented in form QAS028-F07-00, (b) (4) Sampling Intimation Details, that he started collecting (b) (4) sample (b) (4) at (b) (4) and (b) (4) sample (b) (4) at (b) (4) However, the biometric access control system that limits access to the area (Room (b) (4) Block) does not show that employee ID: (b) (6) entered that room during the sampling period.

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B. Similarly, on (b) (4) your Quality Assurance employee ID: (b) (6) documented in form QAS028-F07-00, (b) (4) Sampling Intimation Details, that he started collecting (b) (4) (b) (4) sample (b) (4) at (b) (4) and (b) (4) sample (b) (4) at (b) (4) Nonetheless, the biometric access control system that limits access to the area (Room (b) (4) (b) (4) Block) does not show that employee ID: (b) (6) entered that room during the sampling period.

C. On (b) (4) your Quality Assurance employee ID: (b) (6) documented in form QAS028-F07-00, (b) (4) Sampling Intimation Details, that he started collecting (b) (4) sample (b) (4) at 9:41:11am. But the biometric access control system that limits access to the area (Room (b) (4) Block) shows that your employee ID: (b) (6) entered the room at 9:41:28am.

During my interview with your QA employee ID: (b) (6) he explained that he always enters the sampling room via the (b) (4) door, using the biometric access panel, performs (b) (4) sampling by himself, and that the time it takes him from entering the room to start any (b) (4) sample collection is approximately (b) (4)

D. On (b) (4) your Quality Assurance employee ID: (b) (6) documented in form QAS028-F07-00, (b) (4) Sampling Intimation Details, that he started collecting (b) (4) samples (b) (4) at (b) (4) respectively. However, the biometric access control system that limits access to the area (b) (4) Block) shows that employee ID: (b) (6) entered the room at 12:52pm.

During my interview with your QA employee ID: (b) (6) he explained that he always entered the room via the (b) (4) door, using the biometric access panel, that he always performs (b) (4) sampling by himself, and that the time it takes him from entering the room to starting any (b) (4) sample collection is approximately (b) (4)

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(b) (4) routine samples collected by your Quality Assurance (QA) personnel are tested by your Quality Control (QC) laboratory for microbiological analysis, Bacterial Endotoxin Test (BET), chemical analysis, and (b) (4) to ensure that (b) (4) meets established specifications for use in the manufacturing areas (b) (4) of your (b) (4) (b) (4) Blocks. Although these discrepancies were discussed with Quality Assurance managers, no investigation was initiated to determine why the Junior Executive QA employees were not physically present in the area during sample collection and to establish actions to prevent recurrence.

OBSERVATION 5

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that in-process materials conform to appropriate standards of identity, strength, quality and purity.

On November 17, 2025, we observed the preparation and reading of the Bacterial Endotoxin Test (BET) following your procedure titled "Bacterial Endotoxin Test by Gel Cloth Method", GTP Number: GTP009-01, Effective Date: March 15, 2025, and during our assessment the following deficiencies were identified:

A. Your microbiologist performing the Bacterial Endotoxin Test (BET) gel formation reading for routine (b) (4) sampling points: (b) (4) (b) (4) (b) (4) transferred the gel-clot sample tubes from the incubator to the waste container in a single rapid motion during microbiological analysis, without the crucial pause required to inspect the firmness of the gel for endotoxin detection.

At the same time, a second QC Microbiologist/Analyst acting as a verifier, observed the primary microbiologist rapid assessment and verified the BET results at a distance and angle that failed to ensure

that he could accurately observe and confirm the results at the time that the task was being performed and documented. Despite this basic deficiency, the secondary analyst signed off on the verification.

B. For the BET gel formation reading for routine (b) (4) the results of Positive Control (PC) and Product Positive Control (PPC) for samples (b) (4) (b) (4) were invalid because no gel formation was observed. Your firm-initiated deviation number DEV/MB/25-014 on November 17, 2025, and identified that the root causes for the discrepant results were that the analyst missed a vial tap on the lysate prior to reconstitution and improper timing for rehydration. Deviation Report DEV/MB/25-014 is inadequate, since the identified causes lack scientific data to demonstrate that such analytical practices during sample preparation could alter the results and cause the deviation.

According to your Microbiology Manager, during the preparation of the Control Standard Endotoxin Solution (CSE) for the BET, a minimum of (b) (4) time is required to ensure that the final concentration of the dilution is not affected (Positive Control). However, this critical step is not defined in your GTP Number: GTP009-01. Moreover, this (b) (4) time is not being recorded to ensure that it is always met.

Since November 2023, your firm has approximately performed the BET on a total of (b) (4) sample sets, encompassing (b) (4) different sterile (b) (4) products (b) (4) (b) (4) (b) (4) intended for the U.S. market, and no discrepant/atypical/invalid results have been observed. Additionally, the QC Microbiology Analyst associated to Deviation Report DEV/MB/25-014 has performed this test for a total of approximately (b) (4) samples without any incident.

OBSERVATION 6

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Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Your firms design and controls to prevent microbiological contamination of sterile drug products in the (b) (4) manufacturing lines are deficient and pose a potential risk to product sterility. On November 20-21, 2025, we evaluated the assembly and filling process in your (b) (4) line. We observed a flawed design in your filling lines, and poor assembling process and operators' aseptic behaviors.

The (b) (4) filling lines include a (b) (4) conveyor (ISO 5 area) after the stoppering zone. The manufacturing operators and microbiologists are continuously crossing this conveyor during assembly and filling processes, including the (b) (4) used to transfer the EM plates and equipment. In addition, no continuous non-viable particle counter isokinetic probe is present at this (b) (4) conveyor. This activity constitutes a flow of personnel from ISO 7 area through ISO 5 without real-time monitoring, posing a contamination risk.

A. There is no assurance that the existing personnel flow within the vial filling rooms (b) (4) (b) (4) is adequately designed to prevent microbial contamination.

The following is not an exhaustive listing of the deficiencies observed on November 20, 2025, during the trial batch of sterile (b) (4) in the (b) (4) filling line:

1. We observed inadequate aseptic practice when performing the EM settle plate change. For example, your microbiologist opened the (b) (4) of the aseptic core (ISO 5) area prior to identifying each settle plate. The (b) (4) remained opened for an extended period of time. This practice unnecessarily exposes the filling line to prolonged intervention duration and potential contamination. This inadequate practice was observed during every EM planned intervention.

Additionally, your microbiologist was observed leaving the (b) (4) LAF to collect the settle plates from (b) (4) bin that was placed in the (b) (4) located in ISO 7 area. Meanwhile, the (b) (4) of the aseptic core remained opened creating a potential breach of ISO 5 aseptic conditions.

2. During the pre-assembling EM monitoring, we observed multiple instances in which your operators performed (b) (4) interventions and failed to sanitize the inner side of (b) (4) During the assembling process, your operator installed (b) (4) that were not adequately sanitized.

3. Your firms' operators were observed passing the (b) (4) from the rear side of the filling line towards the front side of the filling line during the assembling of the (b) (4) During the (b) (4) transferring, we observed that your operators came into direct contact with critical zones, including the (b) (4) area, (b) (4) and the (b) (4) stopper zone potentially compromising the ISO 5 aseptic conditions.

4. There is not an assigned dedicated reject station. We observed that your operators used a (b) (4) (b) (4) bin in the ISO 7 area to dispose the sterile (b) (4) bags. This container is also used as a reject station during aseptic filling operations.

5. We observed a broken vial corrective intervention in the (b) (4) (Zone 1). The operator did not remove the vials near the impacted vials. He only removed the two (2) broken vials from the filling line. Additionally, we observed a vial breakage in the (b) (4) (Zone 2) and your operator only removed the broken the vial. Vials near the impacted vial were not removed.

On November 21, 2025, during the trial batch of sterile (b) (4) in the (b) (4) filling line the following deficiencies were observed:

1. Your manufacturing operator failed to ensure that [redacted] used for in-process [redacted] test was not suitable for its intended use. The manufacturing operator was observed using the [redacted] without fully closing the [redacted] He also was observed printing the [redacted] results while the [redacted] was fluctuating and unstable. In addition, the [redacted] was located underneath of air supply unit, altering the [redacted] readings.

2. We observed your operator [redacted] the vial seals into the [redacted] without sanitizing the [redacted] prior to introducing them into ISO 5 area of the sealing/capping zone. The [redacted] are transferred from the [redacted] throughout ISO 8 environment and subsequently loaded directly into the [redacted] of the sealing/capping ISO 5 area without sanitization.

OBSERVATION 7

Aseptic processing areas deficient regarding system for monitoring environmental conditions.

Your environmental monitoring program is inadequate in demonstrating ongoing controls of the aseptic manufacturing environment, equipment and facility oversight.

A. Your firm failed to consider in the environmental monitoring program the [redacted] located in Micro/QC building. As per your Microbiology Deputy Manager, this is a [redacted] which is used to receive including but not limited to [redacted] samples, raw materials, packing materials, in-process, stability samples, cleaning validation samples, [redacted] finished product samples and EM plates.

B. Your firm failed to identify with a unique equipment number the [redacted] located in the aseptic filling lines in [redacted] blocks. As per your Senior Executive Production of [redacted] these [redacted] are routinely used for production and environmental monitoring activities within ISO 7 areas. On November 20, 2025, during the non-commercial manufacturing of

sterile (b) (4) in (b) (4) Line (b) (4) we observed approximately (b) (4) unidentified (b) (4) enter the aseptic fill room at different times. There is no traceability of the cleaning and sanitization status of the (b) (4) which impedes investigations of potential contamination and/or environmental excursions.

C. The engineering toolbox used in the (b) (4) block is not monitored adequately. As per your control procedure MB072-07 titled "Microbiological environmental monitoring program in (b) (4) sterile (b) (4) manufacturing block", Effective Date: September 5, 2025, the Grade B Surface monitoring locations, considered for the "Tools box outer surface of tool box located in the component receipt area" is monitored only on the top surface of the toolbox lid; however, your engineering employee is in direct contact with the handle of the lid. Your firm failed to identify and sample the worst-case location of the toolbox which compromises the accuracy of the environmental monitoring assessments.

D. Your firm does not implement effective Corrective and Preventive Actions (CAPAs) to address recurring Environmental Monitoring (EM) excursions with root causes attributed to personnel movement and/or personnel activity in the (b) (4) Block. Specifically, between July 2024 and August 2025, your firm documented multiple EM excursions, in most cases, the CAPA implemented for these events was a "refresher training" on cleanroom behavior and the procedure for entering and exiting Grade B areas, which demonstrates that it was not sufficient to prevent the recurrence of the events.

E. Access to the microbiology laboratory in the (b) (4) block is not appropriately restricted. During the inspectional walkthrough performed on November 19, 2025, firm personnel were observed bypassing the access-controlled card readers installed at the entrance of each internal laboratory room (b) (4) Furthermore, there was no restricted access in the (b) (4) Block (b) (4) (b) (4) entrance. This practice undermines the intended access

restriction and there is no assurance that only authorized personnel enter the (b) (4) microbiology laboratory where (b) (4) incubators are found.

OBSERVATION 8

Batch production and control records do not include complete information relating to the production and control of each batch.

Your firm failed to report all the interventions performed on November 20-21, 2025, during the filling of non-commercial runs of sterile (b) (4) in (b) (4) lines.

A. A new corrective intervention of broken vial in the (b) (4) conveyor of the (b) (4) filling line was not documented. This intervention was observed at approximately (b) (4)

B. In (b) (4) filling line, (b) (4) corrective interventions identified as "clearing the jammed (b) (4) stoppers in the (b) (4) " were not documented. These interventions were observed at approximately (b) (4) This corrective intervention was performed (b) (4) times during the filling of the sterile (b) (4) However, the maximum validated frequency for this intervention in the media fill is (b) (4) times.

OBSERVATION 9

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the equipment to produce aseptic conditions.

A. Your disinfectant efficacy study protocol and report MIP-MIR/MB/22/004-00, approved on April 26, 2022, and July 15, 2022, respectively are inadequate in that failed to document the contact times

(e.g., (b) (4) evaluated during the study. Moreover, there is no evidence about the timer and/or stopwatch used to monitor the selected times.

Similarly, the following disinfectant efficacy studies MIP-MIR/MB(b) (4) 009-00, MIP-MIR/MB(b) (4) 003-00 and MIP- MIR/ME(b) (4) 001, initiated in (b) (4) respectively to evaluate the efficacy of the disinfectants on various surfaces materials of controlled and critical clean rooms do not document the validated (b) (4) contact time.

Additionally, on November 20, 2025, during the non-commercial run of sterile (b) (4) in the (b) (4) Line (b) (4) we observed your operators using an HMI mouse for adjusting process parameters. This device has not been considered in your disinfectant efficacy studies. Moreover, this HMI mouse is cleaned with a dry lint-free cloth and there is no empirical data to demonstrate this removes potential contaminants.

B. On November 21, 2025, during the non-commercial run of sterile (b) (4) in the (b) (4) Line, we observed your operators using a touch pen when adjusting process parameters in the HMI. Your procedure PD220-03 titled, "Cleaning and Sanitization Procedure for Production Area and Drain Point", Effective Date: May 05, 2025, does not specify the sanitization of such accessory. Moreover, your Microbiology Deputy Manager stated the touch pen is not included in the environmental monitoring program.

OBSERVATION 10

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Your firm failed to assign an appropriate "guest" role access to the external customer personnel who performed method transfer activities of (b) (4) GC analysis and (b) (4) Assay & RS analysis in your GC and HPLC instruments on October 7, 2025, and October 14, 2025, respectively.

Your customer was assigned with an "analyst" role and had access to work with your Empower 3.8.1 software HPLC/GC analytical data processing system. On November 17, 2025, when reviewing the audit trail from computer COMQC041 for HPLC/GC instruments, we observed that two (2) customers were assigned with the "analyst" role in Instrument Lab-(b) (4) According to form QC089-F01-00, "Empower Requisition Form for User ID Creation, Modification and Activation", the two (2) customer had active accounts since October 2025. As per your QC Deputy Manager, the method transfer activities were completed on October 17, 2025; however, we found that the accounts are still active.

Furthermore, your procedure QCS065-00 titled, "Administration of Empower 3.8.1 Chromatography Software", Effective Date: October 13, 2025, is inadequate as step (b) (4) states that "API Vendor Analysts involved in method transfer activities should have a user ID created with the Analyst user type". Your procedure does not describe appropriate controls to ensure that customers have user roles with minimum access necessary to perform their activities, and a specific deactivation timeframe.

OBSERVATION 11

Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically, your firm failed to approve control procedures to demonstrate critical laboratory equipment are consistently monitored. Your control procedure titled "Operation, Cleaning and Sanitization of (b) (4) (b) (4) Incubator and (b) (4) Cooling Chamber", SOP Number: MBS007-00, Effective

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Chennai, Tamil Nadu, 602117, India	Sterile Drug Product Manufacturer

Date: September 26, 2025, does not define the handling of alarms due to temperature/humidity excursions that may occur in your microbiology laboratory incubators.

On November 17, 2025, we observed during the inspectional walkthrough of your microbiology laboratory that your (b) (4) incubators (b) (4) alarm system is inadequate. The current alarm system fails to notify laboratory personnel or engineering employees who are not physically in the laboratory about any temperature or humidity excursion. As explained by your Microbiology Manager, the actual alarm system only provides an audible cue and only employees present inside of the microbiology laboratory incubator room could acknowledge an ongoing environmental condition excursion. Furthermore, he explained that the current laboratory practice is to acknowledge the alarms, but the acknowledgement is not documented and does not address why the alarm occurred. Therefore, your current procedure SOP Number: MBS007-00, does not ensure a continuous oversight of the incubators and a prompt detection of equipment performance issues.

Your (b) (4) incubators (b) (4) are used to store samples that include Environmental Monitoring (EM) exposure plates, subcultures, Growth Promotion Test, isolation identification plates, (b) (4) samples and media storage.

J. E. M. 11/27/2025

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	AMH	Alan A. Rivera, Investigator Jose E. Melendez, DDC Investigator Angelica M. Hernandez, Investigator	November 27, 2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."